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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,945

04/13/2006

Jan Bergstrom

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GE HEALTHCARE BIO-SCIENCES CORP.  
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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,945	<b>Applicant(s)</b> BERGSTROM ET AL.	
	<b>Examiner</b> KATHERINE ZALASKY	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-18,20-52,54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 16-18,20-52,54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in the reply filed on 16 December 2008 is acknowledged.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1, 3-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al. (US 6,426,315).**

Regarding **claim 1**, Bergstrom et al. discloses a separation matrix comprising a porous support comprising porous particles (C1/L6-10); and ligands coupled to the surfaces of said porous support (C3/L37-39, C4/L58-C5/L7), wherein the ligands provide at least one chemical gradient in the support (C1/L63-67), further wherein the chemical gradient(s) extend between the center and exterior surface of each porous particle (C1/L63-67).

Bergstrom et al. does not explicitly disclose the matrix wherein said at least one chemical gradient is a continuous and smooth gradient. However, it is well known in the art that gradients may either be designed to be stepwise or continuous (as evidenced by Carlsson et al., US 6,528,322, C6/L63-66). Therefore, it would have been obvious to one having ordinary skill in the art to choose a continuous and smooth gradient from a finite number of identified, predictable ways to form a gradient.

Regarding **claims 3-9**, modified Bergstrom discloses all of the claim limitations as set forth above. Additionally, Bergstrom et al. discloses the separation matrix wherein:

- at least one chemical gradient is a ligand density gradient formed by a changing density of ligands on the support (C6/L17-26)
- two or more chemical gradients are present in the support and at least one gradient is a ligand density gradient (C6/L17-26, one or more layers with different functionalities, and varying the degree of substitution)
- in the ligand density gradient(s), the ligand concentration increases towards the center of the support (C6/L17-26)
- in the ligand density gradient(s), the ligand concentration decreases towards the center of the support (C6/L17-26)
- the matrix is a chromatography matrix comprised of a plurality of essentially spherical particles (C4/L20-38), wherein each particle presents one or more chemical gradient(s) perpendicular to the direction of the liquid flow applied in chromatography (C1/L63-67, the gradient on a

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spherical particle, therefore the gradient will extend radially and at least one gradient will exist perpendicular to an applied liquid flow)

- at least one gradient is the result of varying pKa values of functional groups of the ligands present on the support (C3/L37-39, C4/L58-C5/L7, each different ligand has a different pKa value)
- at least one chemical gradient is the result of a varying net charge of the ligands present on the support (C5/L17-24, Example 3, C10/L26-29)

Regarding limitations recited in **claim 7** which are directed to a manner of using the separation matrix, such as applying a flow of liquid in chromatography, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding **claims 11-15**, modified Bergstrom discloses all of the claim limitations as set forth above. Additionally, Bergstrom et al. discloses the separation matrix wherein:

- the ligands present on the porous support provide at least two different functionalities (C3/L37-39)
- said functionalities are selected from the group consisting of cation exchange ligands, anion exchange ligands, hydrophobic interaction chromatography (HIC) ligands, reversed phase chromatography (RPC) ligands, immobilized metal chelating ligands (IMAC), thiophilic ligands, and affinity ligands (C4/L58-C5/L7)
- said at least two different functionalities are present on the same ligand (C5/L25-34, ligand may be an IgG binding protein, made up of amino acids)

- the ligands present zwitterionic functionalities (C5/L25-34, ligand may be an IgG binding protein, made up of amino acids, which have zwitterionic functionalities)
- said at least two different functionalities are present on different ligand kinds, and each such ligand kind provides a separate chemical gradient within the support (C1/L63-67, C3/L37-39)

***Response to Arguments***

6. Applicant's arguments with respect to **claims 1-15** have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on Monday-Thursday, 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KZ/

3 February 2009

/Krishnan S Menon/

Primary Examiner, Art Unit 1797